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No. 95-1644

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

COLLAGEN, CORPORATION,
Petitioner,

v.

CHARLOTTE KENNEDY, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

REPLY BRIEF

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REPLY BRIEF

DISCUSSION

1. The issue in this case is whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration ("FDA") has found to be safe and effective and has approved for marketing pursuant to the statutory premarket approval ("PMA") process under 21 U.S.C. § 360e(c). The Ninth Circuit decided this issue in a manner that squarely conflicts with decisions by the First, Third, Fifth, Seventh, and Eighth

Circuits. This conflict may or may not be effectively resolved by this Court's forthcoming decision in *Lohr v. Medtronic, Inc.*, Nos. 95-754 and 95-886, *argued*, April 23, 1996. If the conflict is not resolved in *Medtronic*, certiorari should be granted in this case to lay to rest a recurrent and important question of federal preemption.

In opposing certiorari, respondents do not deny the existence of a conflict. They argue only that the decision below was right (and, by implication, that the decisions of all other circuits to have considered this issue were wrong). Of course, for the reasons stated in the petition, Collagen disagrees. But the disagreement between the parties, mirroring the disagreement among the circuits, simply highlights the fact that this case involves a conflict that this Court ultimately must resolve. The circuits should not be left at loggerheads over a question of federal law that is so commonly litigated and has such significant consequences for a major regulated industry.

2. Respondents make three purportedly factual points that call for a reply.

a. Respondents point out, as if it matters, that FDA promulgated its final regulations setting forth the procedures to be followed in filing an application for premarket approval under 21 U.S.C. § 360e(c) only in 1986, several years after Zyderm and many other medical devices already had been approved pursuant to the PMA process. Br. in Opp. 4. That in no way detracts from the rigor of the PMA process as administered prior to 1986. Lacking established procedures, the FDA had asked applicants to "follow the pertinent parts of the regulations for new drug applications," Erickson Decl., Ex. 1, and to "us[e] the PMA formatting suggested by the Bureau of Medical Devices." *Id.*, Ex. 2. Collagen did so. *Id.* The statute itself sets forth the basic substantive requirements that a manufacturer must meet to secure premarket approval, see Pet. 4-5, and the record is

clear both that FDA enforced those requirements and that Collagen met them. Erickson Decl. 1-5.

b. Respondents state that although the FDA does impose requirements with respect to Collagen's labeling for Zyderm, Collagen is free to add "warnings, contraindications, or side effects." Br. in Opp. 5. That statement is factually inaccurate and legally irrelevant.

Respondents' statement is factually inaccurate because Collagen is empowered to add warnings or information about contraindications or side effects only after (1) filing a PMA supplement with the FDA identifying the proposed changes, explaining the basis for them, and stating when they are to go into effect, and (2) receiving an acknowledgement from the Bureau of Medical Devices. 21 C.F.R. § 814.39(d)(1).

Respondents' statement is legally irrelevant because the MDA preemption statute bars the states from imposing any requirement "which is different from, or in addition to, any [FDA] requirement." 21 U.S.C. § 360k(a). A requirement, imposed through state common law, that Collagen add warnings not required by the FDA plainly would be "in addition to" the labeling requirements that the FDA does impose. *See King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993) (Aldridge & Campbell, JJ., concurring).

c. Respondents refer to a seizure by the FDA of Collagen's Zyderm devices in 1991. Br. in Opp. 5-6. This reference is purely inflammatory. The seizure itself was a trivial episode, it occurred long after the events giving rise to this litigation, it has nothing to do with respondents' claims, and for these reasons there understandably is no discussion of it in the record. The seizure took place merely because a line of text (nine words) had been inadvertently omitted in 1991 from the package inserts that accompanied the product. This problem, which was promptly rectified, has no bearing on the question presented in this case.

CONCLUSION

The petition should be held pending disposition of *Medtronic*; it should then be granted to the extent that the preemption issues it raises are left unresolved by the Court's decision in that case.

Respectfully submitted,

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